UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

SUBJECT: Rationale for selected US ACE Dredging Permit Conditions

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DATE: November 02, 2009

This memorandum provides U.S. Environmental Protection Agency (EPA) rationale for certain conditions being requested on US Army Corp of Engineer (USACE) dredging permits near the San Jacinto River Waste Pits Superfund site. Justification is being provided for:

1. **Required sediment sample number and distribution**

   One sediment composite core sample is required per each 5,000 cubic yards (cy) of dredged material. One sample per 5,000 cy follows Port of Houston Authority (PHA) requirements for sediment sampling that can be found on their website at http://www.portofhouston.com/pdf/channel/PHASedimentProcedures.pdf (also see Attachment A) EPA believes that this core sample may be a composite sample as dredged material is likely to be mixed and disposed of (where applicable) as bulk material.

   An additional discrete sediment sample is required from the upper six inches of sediment surface to remain/be exposed after dredging activities including planned overdredges or advanced maintenance. This sample assures that dredging activities create acceptable sediment exposure.

2. **Required sediment sample analysis**

   Laboratory sample analysis should follow EPA methods 1613, 8280b or 8290a. These methods are approved for EPA investigations and provide consistency through EPA programs.

Results should be reported as 2,3,7,8-tetrachloro-p-dibenzodioxin (2,3,7,8-TCDD) Toxicity Equivalents (TEQs) and 2,3,7,8-TCDD organic carbon normalized or 2,3,7,8-TCDD non-organic carbon normalized concentrations. Reporting as TEQs and 2,3,7,8-TCDD concentrations allows EPA flexibility in making comparisons with existing databases.

EPA recommends TEQ calculations be performed using Toxicity Equivalence Factors (TEFs) published by the World Health Organization (WHO) in 2005 (see Attachment B)

3. Conditions determination

3a. Samples >1000 ng/kg TEQ shall be disposed of in a hazardous waste landfill.

3b. Samples >33 ng/kg TCDD organic carbon normalized and <1000 TEQ; or >0.45 ng/kg non-organic carbon normalized and <1000 TEQ shall be disposed of in a hazardous waste landfill or an upland confined disposal area.

3c. Samples <33 ng/kg TCDD organic carbon normalized; or <0.45 ng/kg non-organic carbon normalized shall have no restrictions on disposal location.

Due to the numerous health advisories for fish consumption in the Houston Ship Channel and San Jacinto River, and the lack of formal risk assessment, EPA took a conservative human health protective approach. 1000 ng/kg TEQ is the maximum recommended concentration for protection of human health for residential soil (see Attachment C).

33 ng/kg 2,3,7,8-TCDD organic carbon normalized or 0.45 ng/kg 2,3,7,8-TCDD non-organic carbon normalized represent a conservative risk estimate for protection of human health from consumption of contaminated fish or crab. Calculations were based on the following:

- cancer slope factor for 2,3,7,8-TCDD = $1.56E \times 10^{5}$ per mg/kg/day
- TEF = 1
- 1×10^{-5} excess lifetime cancer risk level
- 70 kg body weight
- 0.015 kg/day fish consumption rate
- a median BSAF of 8.88×10^{-3} for 2,3,7,8-TCDD in catfish
- 1.35% average total organic carbon (TOC) in the Houston Ship Channel

ATTACHMENT A

Port of Houston Authority
Sediment Sampling Requirements

One sediment core should be taken for approximately every 500 linear feet over the dredge prism and represent a maximum sediment volume of 5,000 cubic yards.

Outfalls should have sediment samples obtained as representative of that area.

Core samples should be at least as great as the proposed dredge depth. Sediment samples can be homogenized, for example a four foot core can result in one sediment sample and a nine foot core would become two sediment samples.

The Port of Houston Authority is available to review sampling plans and locations prior to field activities, if necessary.

A list of sediment sampling consultants and contractors will be provided upon request.

The table below lists the required sediment sample analytical constituents and parameters.

The Port of Houston Authority contracts analytical sediment sampling to the following laboratory, which is familiar with requirements and is able to meet parameters:

e-Lab Analytical, Inc., Shannon Tyrell/Sally Roan: 281-530-5656

Upon the completion of sediment sampling activities and analysis, an interested party must submit a Sampling Analysis Plan with location map and analytical data to the Port of Houston Authority Environmental Affairs Department for approval/acceptance into a confined disposal facility.

If you have any questions on your sediment sampling activities and PHA policies, please contact Dana Blume at 713-670-2805.

Chemical	CAS Number [1]	Sediment Reporting Limit Required for Comparison to Ecological Screening Thresholds[(3)]	Analysis Method
CONVENTIONALS			
Total Solids (%)			Pg.17 (2)
Total Volatile Solids (%)			Pg.20 (2)
Total Organic Carbon (%)			DOE (3)
Grain Size			Modified ASTM with Hydrometer
METALS (mg/kg)			
Antimony	7440-36-0	0.3	GFAA
Arsenic	7440-38-2	16	GFAA
Cadmium	7440-43-9	0.7	GFAA
Chromium	7440-47-3	3.0	GFAA
Copper	7440-50-8	36	ICP
Lead	7439-92-1	38	ICP
Mercury	7439-97-6	0.3	7471
Nickel	7440-02-0	28	ICP
Silver	7440-22-4	1.3	GFAA
Zinc	7440-66-6	80	ICP
ORGANOMETALLIC COMPOUNDS (mg/kg)			
*Tributyltin	56573-85-4	0.1	
ORGANICS (mg/kg)			
Total LPAH			
Naphthalene	91-20-3	0.84	8270
Acenaphthylene	208-96-8	1.2	8270
Acenaphthene	83-32-9	20	8270
Fluorene	86-73-7	30	8270
Phenanthrene	85-01-8	3.0	8270
Anthracene	120-12-7	0.15	8270
2-Methylnaphthalene	91-57-6	0.84	8270
Total HPAH			
Fluoranthene	206-44-0	1.2	8270
Pyrene	129-00-0	1.2	8270
Benz(a)anthracene	56-55-3	1.2	8270
Chrysene	218-01-9	1.2	8270
Benzofluoranthenes (b+k)	205-99-2 207-08-9	1.2	8270
Benzo(a)pyrene	50-32-8	1.2	8270
Indeno(1,2,3-c,d)pyrene	193-39-5	1.2	8270
Dibenz(a,h)anthracene	53-70-3	1.2	8270
Benzo(g,h,i)perylene	191-24-2	1.2	8270
Chlorinated Hydrocarbons			
1,3-Dichlorobenzene	541-73-1	1.5	8260
1,4-Dichlorobenzene	106-46-7	1.5	8260
1,2-Dichlorobenzene	95-50-1	1.5	8260
1,2,4-Trichlorobenzene	120-82-1	1.5	8270

Port of Houston Authority

Sediment Sampling
Listing of Chemicals of Concern

Chemical	CAS Number [1]	Sediment Reporting Limit Required for Comparison to Ecological Screening Thresholds[(3)]	Analysis Method
Hexachlorobenzene (HCB)	118-74-1	1.5	8270
Phthalates			
Dimethyl phthalate	131-11-3	5.0	8270
Diethyl phthalate	84-66-2	5.0	8270
Di-n-butyl phthalate	84-74-2	5.0	8270
Butyl benzyl phthalate	85-68-7	5.0	8270
Bis(2-ethylhexyl) phthalate	117-81-7	5.0	8270
Di-n-octyl phthalate	117-84-0	5.0	8270
Phenols			
Phenol	108-95-2	2.5	8270
2-Methylphenol	95-48-7	2.5	8270
4-Methylphenol	106-44-5	2.5	8270
2,4-Dimethylphenol	105-67-9	2.5	8270
Pentachlorophenol	87-86-5	2.5	8270
Miscellaneous Extractables			
Benzyl alcohol	100-51-6	NA	8270
Benzoic acid	65-85-0	37	8270
Dibenzofuran	132-64-9	NA	8270
Hexachloroethane	67-72-1	0.034	8270
Hexachlorobutadiene	87-68-3	0.0074	8270
N-Nitrosodiphenylamine	86-30-6	20	8270
Volatile Organics			
Trichloroethene	79-01-6	5.0	P&T
Tetrachloroethene	127-18-4	0.10	P&T
Ethylbenzene	100-41-4	1.5	P&T
Total Xylene (sum of o-, m-, p-)	95-47-6 108-38-3 106-42-3	5.0	P&T
Pesticides			
Total DDT (sum of 4,4'-DDD, 4,4'-DDE and 4,4'-DDT)	72-54-8 72-55-9 50-29-3	0.5	--
Aldrin	309-00-2	0.003	8081
Alpha-Chlordane	12789-03-6	0.0015	8081
Dieldrin	60-57-1	0.00094	8081
Heptachlor	76-44-8	0.035	8081
Gamma-BHC (Lindane)	58-89-9	0.0025	8081
Total PCBs	---	2.5[2]	8081

Source: USACE
[1] Chemical Abstract Service Registry Number.

[2] This value is normalized to total organic carbon, and is expressed in mg/kg (TOC normalized)

[3] Some of these values should be adjusted if there is a concern regarding potential beneficial use of groundwater. Refer to TCEQ groundwater screening levels. Analytical testing results should be reported on a dry weight basis.

* Tributyltin must be sampled at shipyard locations – current and historical.

ATTACHMENT B

September 1, 2009

Recommended Toxicity Equivalency Factors (TEFs) for Human Health Risk Assessments of Dioxin and Dioxin-Like Compounds: EXTERNAL REVIEW DRAFT

Prepared by Risk Assessment Forum

NOTICE

THIS DOCUMENT IS AN EXTERNAL REVIEW DRAFT. It has not been formally released by the U.S. Environmental Protection Agency and should not at this stage be construed to represent Agency Policy. It is being circulated for comment on its technical accuracy and policy implications.

NOTICE

This report is an external draft for review purposes only and does not constitute Agency policy. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

ABSTRACT

This document describes the U.S. Environmental Protection Agency's (U.S. EPA's) updated approach for evaluating the human health risks from exposures to environmental media containing dioxin-like compounds (DLCs). Dioxin and DLCs are structurally and toxicologically related halogenated aromatic hydrocarbons. Traditionally, the Toxic Equivalency Factor (TEF) Methodology, a component mixture method, has been used to evaluate human health risks posed by these mixtures. The U.S. EPA recommends the use of the consensus TEF values for 2,3,7,8-tetrachlorodibenzo-*p*-dioxin and DLCs published in 2005 by the World Health Organization. The U.S. EPA recommends these TEFs be used for all effects mediated through aryl hydrocarbon receptor binding by the DLCs including cancer and non-cancer effects. Using information that summarizes the range of relative toxicities of the DLCs, the U.S. EPA suggests that conduct of a sensitivity analysis be considered to illustrate the impact the TEFs have on the predicted risk. The U.S. EPA will update these recommendations in the future based on the evaluation of new toxicity data for

the DLCs and the results of new consensus processes undertaken to update the TEF approach.

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LIST OF ABBREVIATIONS

AHR	aryl hydrocarbon receptor
DLC	dioxin-like compound
ECEH	European Centre for Environmental Health
ED_{50}	effective dose that causes an effect in 50% of the test units
IPCS	International Programme on Chemical Safety
NAS	National Academy of Science
ReP	relative potency or relative effect potency
ReP_{1997}	World Health Organization ReP database developed in 1997
TCDD	2,3,7,8-tetrachlorodibenzo-*p*-dioxin
TEF	toxic equivalency factor
TEQ	toxic equivalence
U.S. EPA	U.S. Environmental Protection Agency
WHO	World Health Organization

LIST OF ABBREVIATIONS OF DIOXINS AND DIOXIN-LIKE COMPOUNDS

Polychlorinated biphenyls:

TCB	tetrachlorinated biphenyl
PeCB	pentachlorinated biphenyl
HxCB	hexachlorinated biphenyl
HpCB	heptachlorinated biphenyl
OCB	octachlorinated biphenyl
PCB	polychlorinated biphenyl

Polychlorinated dibenzo-p-dioxins:

TCDD	tetrachlorinated dibenzo-*p*-dioxin
PeCDD	pentachlorinated dibenzo-*p*-dioxin
HxCDD	hexachlorinated dibenzo-*p*-dioxin
HpCDD	heptachlorinated dibenzo-*p*-dioxin
OCDD	octachlorinated dibenzo-*p*-dioxin
PCDD	polychlorinated dibenzo-*p*-dioxin

Polychlorinated dibenzofurans:

TCDF	tetrachlorinated dibenzofuran
PeCDF	pentachlorinated dibenzofuran
HxCDF	hexachlorinated dibenzofuran
HpCDF	heptachlorinated dibenzofuran
OCDF	octachlorinated dibenzofuran
PCDF	polychlorinated dibenzofuran

KEY TERMS

Dioxin-like: A description used for compounds that have chemical structures, physico-chemical properties and toxic responses similar to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD). Because of their hydrophobic nature and resistance towards metabolism, these chemicals persist and bioaccumulate in fatty tissues of animals and humans. Certain members of the dioxin, furan, and polychlorinated biphenyl (PCB) family are termed “dioxin-like” in this document and are assigned TEF values.

Index Chemical: The chemical selected as the basis for standardization of toxicity of components in a mixture. The index chemical must have a clearly defined dose-response relationship. For DLCs, TCDD is typically specified as the index chemical.

Relative Potency (ReP): The ratio of the potency of a compound to the standard toxicant in that specific study; a concept similar to toxic equivalency but based on a single study, species, or matrix, etc., and not averaged to obtain a general toxic equivalency value.

TEFs: TEFs are estimates of compound-specific toxicity relative to the toxicity of an index chemical (typically, TCDD). TEFs are the result of expert scientific judgment using all of the available data and taking into account uncertainties in the available data.

TEQ: Toxic equivalence (TEQ) is the product of the concentration of an individual DLC in an environmental mixture and the corresponding TCDD TEF for that compound.

PREFACE

This document updates the U.S. EPA's approach for evaluating the human health risks from exposures to environmental media containing dioxin and dioxin-like compounds (DLCs). It is intended for guidance only. It does not establish any substantive "rules" under the Administrative Procedure Act or any other law and will have no binding effect on U.S. EPA or any regulated entity. Rather, it represents a statement of current policy. The U.S. EPA's National Center for Environmental Assessment developed the initial draft of this document, which was then reviewed and completed by a Technical Panel under the auspices of U.S. EPA's Risk Assessment Forum. The Risk Assessment Forum was established to promote scientific consensus on risk assessment issues and to ensure that this consensus is incorporated into appropriate risk assessment guidance. To accomplish this, the Risk Assessment Forum assembles experts from throughout EPA in a formal process to study and report on these issues from an Agency-wide perspective.

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This document was prepared by authors from U.S. EPA's Office of Research and Development and was then reviewed and completed by a Technical Panel under the auspices of U.S. EPA's Risk Assessment Forum.

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INTRODUCTION

This document describes the U.S. Environmental Protection Agency's (U.S. EPA's) updated approach for evaluating the human health risks from exposures to environmental media containing dioxin and dioxin-like compounds (DLCs). Dioxin and DLCs, including polychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs), are structurally and toxicologically related halogenated dicyclic aromatic hydrocarbons.[2] Because the combined effects of these compounds have been found to be dose additive, the U.S. EPA has recommended use of the Toxic Equivalency Factor (TEF) Methodology and the World Health Organization's (WHO's) TEFs to evaluate the risks associated with exposure to mixtures of these compounds for human health (U.S. EPA, 1989, 2003) and ecological risk assessments (U.S. EPA, 2008). The WHO has used a process based on scientific consensus to develop TEFs for mammals, birds, and fish and has re-evaluated them on a schedule of approximately every five years (Ahlborg et al., 1994; Van den Berg et al., 1998, 2006; also see WHO's website for the dioxin TEFs, available at: http://www.who.int/ipcs/assessment/tef_update/en/). In this document, the U.S. EPA is updating its human health approach by adopting the mammalian TEFs for DLCs recommended in the WHO's 2005 reevaluation of TEFs for human exposures to DLCs (Van den Berg et al., 2006).

[2] For further information on the chemical structures of these compounds, see U.S. EPA (2003, 2008).

THE TEF METHODOLOGY

This section briefly describes the TEF methodology, which is based on the concept of dose addition. Application of this methodology in human health risk assessment has been described and reaffirmed for use by the Agency in U.S. EPA's Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (U.S. EPA, 2000). Under dose addition, the toxicokinetics and the toxicodynamics of all components are assumed to be similar and the dose-response curves of the components of a mixture are assumed to be similarly shaped. Following these assumptions, the combined toxicity of the individual components can be estimated using the sum of their doses, which are scaled for potency relative to that of another component of the mixture for which adequate dose-response information is available (U.S. EPA, 2000).

In practice, the scaling factor for each DLC is typically based on a comparison of its toxic potency to that of a designated index chemical. For DLCs, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) is typically specified as the index chemical. The index chemical is well-studied toxicologically and must have a dose-response function to apply the methodology to an environmental mixture. The toxicological data considered for these comparisons of toxic potency are from both *in vitro* and *in vivo* studies as well as structure-activity relationships and are based on the following classes of measure: biochemical changes, toxicity and carcinogenicity. A comparative toxicity measure from an individual toxicity assay is termed an estimate of relative potency

(ReP).[3] Based on the RePs that may be estimated from multiple toxicological assays, each individual PCDD, PCDF, and PCB is assigned a single scaling factor termed the TEF. By definition, the TEF for TCDD is 1.0 (U.S. EPA, 1989, 2000, 2003, 2008; Van den Berg et al., 1998, 2006).

To apply TEFs to an environmental mixture of DLCs, each individual compound's exposure concentration is multiplied by its specific TEF, yielding the individual PCDD, PCDF, or PCB dose that is equivalent to a dose of the index chemical, TCDD. These TCDD equivalent doses are then summed. To estimate risk associated with the mixture, this sum, which estimates the total index chemical equivalent dose for the mixture components considered, is compared to the dose-response function for TCDD.

Equation 1 is the formula for calculating exposure concentration for *n* DLCs in a mixture in TCDD toxic equivalence (TEQ). Exposure to the i^{th} individual PCDD, PCDF, or PCB compound is expressed in terms of an equivalent exposure of TCDD by computing the product of the concentration of the individual compound (C_i) and its assigned TEF_i. TEQ is then calculated by summing these products across the *n* DLCs compounds present in the mixture. The TEQ may be compared to the dose-response slope for TCDD and used to assess the risk posed by exposures to mixtures of DLCs.

$$TEQ = \sum_{i=1}^{n} (C_i \times TEF_i) \qquad \text{(Eq. 1)}$$

[3] The term "relative effect potency" (ReP) also is used at times. We distinguish this term from 'relative potency factors' (RPF) method, which is a general dose additive method described in U.S. EPA (2000).

BACKGROUND

Initially, U.S. EPA (1989) recommended the use of the TEF approach for DLCs. Due to limitations in the available toxicity data for the DLCs, a number of additional assumptions were associated with this approach as implemented. Besides the inherent assumption of dose additivity, these assumptions included: the applicability of extrapolations from short-term bioassays to long-term health effects; similarities between interspecies metabolism; appropriateness of high-dose to low-dose extrapolations; and the constancy of TEF relationships for different exposure routes, health endpoints and dose levels (U.S. EPA, 1989, 2000, 2003; see also Birnbaum and DeVito [1995] and Birnbaum [1999]). To capture the uncertainty in these assumptions, all TEFs were provided as order-of-magnitude estimates, and the U.S. EPA described their application as a "useful interim approach" (U.S. EPA, 1989).

A set of guiding criteria were developed subsequently for TEF approaches (Barnes et al., 1991; U.S. EPA, 1991, 2000). These criteria included the development of TEFs through scientific consensus. The assignment of consensus TEFs for the DLCs has been reevaluated as new data have become available (e.g., Ahlborg et al., 1994) and through consensus judgment of expert panels (e.g., WHO deliberations detailed in Van den Berg et al., 1998, 2006). The TEF values published in Van den Berg et al. (1998) were recommended for use by U.S. EPA in its National Academy of Science (NAS) review draft dioxin reassessment (U.S. EPA, 2003). In its review, NAS supported the use of the TEF approach (NAS, 2006), stating that "Even with the inherent uncertainties, the committee concludes that the TEF methodology provides a

reasonable, scientifically justifiable, and widely accepted method to estimate the relative potency of DLCs."

In 2005, a WHO expert panel updated TEF values for DLCs (Van den Berg et al., 2006). They reaffirmed the characteristics necessary for inclusion of a compound in the WHO's TEF approach (Van den Berg et al., 1998). These include

- structural similarity to polychlorinated dibenzo-*p*-dioxins or polychlorinated dibenzofurans;
- capacity to bind to the aryl hydrocarbon receptor (AHR);
- capacity to elicit AHR-mediated biochemical and toxic responses; and
- persistence and accumulation in the food chain.

Van den Berg et al. (2006) also reevaluated the support for assuming dose additivity and observing similarly shaped dose-response curves. Evaluations of a number of studies of DLCs, including a mixture study from the National Toxicology Program that evaluated neoplastic and non-neoplastic endpoints (Walker et al., 2005), led the panel to state that the observed toxicity is consistent generally with these two assumptions underlying the TEF approach. In addition, the NAS supported the use of an additivity assumption in its report on U.S. EPA's NAS review draft dioxin reassessment (U.S. EPA, 2003), concluding that "from an overall perspective, this assumption appears valid, at least in the context of risk assessment" (NAS, 2006).

The TEF values were revised further by evaluating new toxicological data in conjunction with *in vivo* ReP distributions formed using a mammalian ReP database (Haws et al., 2006). The database was comprised of ReP values from all identified

studies that could yield an estimate of an ReP for a DLC; the RePs were not weighted according to study characteristics (e.g., *in vivo, in vitro*, chronic, acute, etc.). Haws and collaborators extended the original WHO ReP database, developed at the Karolinska Institute (ReP_{1997} database) in which some studies were represented more than once in the form of dissertations, conference proceedings, and/or peer-reviewed publications.[4] In the development of a refined ReP database, Haws et al. applied a set of study exclusion criteria to the ReP_{1997} database to identify RePs that likely provided "the most representative measure of a biological response." If a study met any of the exclusion criteria, the RePs derived from the study were not included in the quantitative analyses of all RePs. Haws et al. (2006) modified the ReP_{1997} database using the following exclusion criteria:

- Replicate RePs, when RePs from the same original study were presented in multiple publications
- Multiple RePs from a single study that used different assays to measure the same response. In this case an effort was made to identify the single most representative ReP from a study
- Study included only a single dose level of test and/or reference compound
- Data omitted from the final peer-reviewed publication
- Authors indicated in the original publication that the ReP is not valid due to experimental problems
- Data entry errors

[4] The ReP_{1997} database was used in the WHO-European Centre for Environmental Health (ECEH)/International Programme on Chemical Safety (IPCS) TEF evaluation in 1997 and included not only published manuscripts, but also manuscripts in press, conference proceedings, theses, dissertations, and unpublished studies through June of 1997 that compared compounds to TCDD or PCB 126. Since the ReP_{1997} database was intended to be all inclusive, some studies are represented more than once in the form of dissertations, conference proceedings, and/or peer-reviewed publications.

- ReP based on replicates in an *in vitro* study (average value calculated and retained)
- ReP based on non-AHR-mediated response
- ReP based on non-mammalian species
- Response for test or reference compound not statistically different from controls and not biologically meaningful
- Reference compound (e.g., TCDD) not included in study or in identical study from the same laboratory
- Multiple RePs derived from the same data using different calculation techniques
- Multiple RePs reported for laboratory validation study (samples sent to two different labs for analysis and RePs calculated for both)
- Multiple RePs calculated based on different test conditions
- RePs based on data at end of study and at end of some extended recovery period
- ReP based on mixtures study
- ReP from an unpublished study that could not be obtained

The most recent WHO TEFs were developed using a refined approach. The WHO expert panel considered data from Haws et al. (2006) who present a statistical distribution of the RePs for each DLC, calculated from the assembled *in vivo* and *in vitro* studies that were not eliminated by the exclusion criteria. For each individual DLC, the WHO expert panel examined where the existing TEF value from Van den Berg et al. (1998) fell within the *in vivo* ReP distribution developed in Haws et al. (2006). The panel then updated the TEF, or determined no change was needed, based on its position in the ReP distribution, on new toxicological data, and on expert judgment (Van den Berg et al., 2006). Because the ReP distributions were unweighted, the TEFs were

determined using point estimates from toxicological studies, not by using specific points within the ReP distributions. A stepwise scale was used to assign the TEFs using half order of magnitude increments on a logarithmic scale (e.g., 0.03, 0.1, 0.3, etc.) instead of the increments used in previous efforts (e.g., 0.01, 0.05, 0.1, etc.), with uncertainty assumed to be at least ± half a log.

RECOMMENDATIONS

The U.S. EPA recommends use of the consensus mammalian TEF values from Van den Berg et al. (2006) in the assessment of human health risks posed by exposure to mixtures of TCDD and DLCs. These TEFs are presented in Table 1.

The U.S. EPA agrees with Van den Berg et al. (2006) that the TEFs are most appropriate for dioxin exposures via the oral exposure route and that the bioavailability of DLCs encountered through other sources of exposure need to be evaluated in risk analyses. However, the TEFs may be applied to other exposure routes, (i.e., dermal or inhalation) as an interim estimate. U.S. EPA recommends that, if considered in an assessment, the fractional contribution of dermal and inhalation route exposures to the predicted TEQ be identified.

Dioxin and DLCs are associated with several different human health effects. The U.S. EPA recommends these TEFs be used for all cancer and non-cancer effects that are mediated through AHR binding by the DLCs. U.S. EPA recognizes that this issue will require further evaluation as additional toxicity data become available. Eventually, endpoint-specific TEFs or separate TEFs for systemic toxicity and carcinogenicity endpoints may need to be developed.

Van den Berg et al. (2006) also identified a number of candidate compounds that may need to be included in future developments of TEFs for DLCs:

- PCB 37

- Polybrominated dibenzo-*p*-dioxins and polybrominated dibenzofurans (PBDFs)

TABLE 1

Recommended Toxicity Equivalency Factors (TEFs) for Human Health Risk Assessment of Polychlorinated Dibenzo-*p*-Dioxins, Dibenzofurans and Dioxin-Like Polychlorinated Biphenyls

Compound	TEF
PCDDs	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
PCDFs	
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.0003

TABLE 1 cont.

Compound	TEF
*PCBs**	
3,3',4,4'-TCB (77)	0.0001
3,4,4',5-TCB (81)	0.0003
3,3',4,4',5-PeCB (126)	0.1
3,3',4,4',5,5'-HxCB (169)	0.03
2,3,3',4,4'-PeCB (105)	0.00003
2,3,4,4',5-PeCB (114)	0.00003
2,3',4,4',5-PeCB (118)	0.00003
2',3,4,4',5-PeCB (123)	0.00003
2,3,3',4,4', 5 -HXCB (156)	0.00003
2,3,3',4,4',5'-HxCB (157)	0.00003
2,3',4,4',5,5'-HxCB (167)	0.00003
2,3,3',4,4',5,5'-HpCB (189)	0.00003

Source: Van den Berg et al. (2006); WHO's website on dioxin TEFs, available at: http://www.who.int/ipcs/assessment/tef_update/en/.

*Note: TEFs that were previously assigned to PCB 170 and PCB 180 (Ahlborg et al., 1994) were withdrawn during the WHO-ECEH/IPCS TEF re-evaluation in 1997, and a TEF for PCB 81 was established, such that the number of PCB compounds with TEFs assigned was reduced from 13 to 12 (Van den Berg et al., 1998).

- Mixed halogenated dibenzo-*p*-dioxins and mixed halogenated dibenzofurans
- Hexachlorobenzene
- Polychlorinated naphthalenes and polybrominated naphthalenes
- Polybrominated biphenyls

U.S. EPA will consider an update of the recommendations in this document when TEFs for these candidate compounds are developed. At a minimum, if occurrence or exposure data are available for these candidate compounds, this information should be included in the risk analyses.

For analytic transparency, the U.S. EPA recommends that the fraction of the TEQ attributable to each PCDD, PCDF, or PCB compound be identified in the risk characterization and that the compounds making the largest contributions to the TEQ be specified as appropriate to the assessment. For example, U.S. EPA (2003) notes that the majority of the TEQ (based on Van den Berg et al., 1998) from dietary exposures is typically associated with the concentrations of only five compounds (i.e., TCDD, 1,2,3,7,8-PCDD, 2,3,4,7,8-PeCDF, 1,2,3,6,7,8-HxCDD, PCB 126) whose ReP variability appears to be small relative to other compounds.[5] Thus, if dietary exposures are important to the assessment being conducted, the fraction of the TEQ attributable to these five compounds should be presented and discussed in the risk characterization. In addition, the implications of the fraction of the TEQ attributable to TCDD should be discussed in the analyses because the dose-response data for TCDD are used to

[5] Note that the TEF for 2,3,4,7,8-PeCDF changed from 0.5 to 0.3 from Van den Berg et al., 1998 to 2006, respectively.

evaluate risks, and the confidence in the risk estimate increases with increases in the fraction of the TEQ attributable to TCDD.

The U.S. EPA suggests that a sensitivity analysis be considered when using TEFs in major risk assessments to illustrate the impact the TEFs have on the predicted risk, which is consistent with good risk assessment practices (U.S. EPA, 2000). However, the U.S. EPA recognizes that ranges and appropriate distributions of the uncertainty associated with each TEF will need to be developed to facilitate the conduct of advanced sensitivity analyses and uncertainty analyses. Although limited to the available ReP data (i.e., not necessarily an unbiased sample of equivalent factors), the ReP ranges developed by Haws et al. (2006) may provide a starting point for sensitivity analyses.

Haws et al. (2006) discuss the limitations of the current ReP database for use in quantitative uncertainty analysis. The RePs were calculated using various approaches, ranging from comparing dose-response curves to developing ratios of ED_{50s}[6] to estimating values from graphs of dose-response data. The RePs also represent a wide variety of study types and endpoints, including biochemical changes, systemic toxicity and carcinogenicity; some of these data may provide estimates that are more consistent with individual PCDD, PCDF, or PCB compound toxicity at higher levels of biological organization and such considerations will need to be included in the development of a TEF distribution. Finally, they note a number of issues associated with the dose-response data (e.g., non-parallel dose-response curves, differences in maximal response among PCDD, PCDF, or PCB compounds within a study, incomplete

[6]An ED_{50} is an effective dose that causes an effect in 50% of the test units.

dose-response data due to insufficient dose levels). Despite these challenges, U.S. EPA recognizes that the development of a more refined ReP database and additional examination of the uncertainties inherent in a TEF process would improve TEF-based risk assessments.

CONCLUSIONS

The U.S. EPA recommends use of the consensus mammalian TEF values from Van den Berg et al. (2006) in the assessment of human health risks posed by mixtures of TCDD and DLCs (Table 1). The U.S. EPA will update these recommendations in the future based on the evaluation of new toxicity data for the DLCs and the results of new consensus processes undertaken to update the TEF approach.

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APPENDIX A

RECOMMENDED TOXICITY EQUIVALENCY FACTORS (TEFS) FOR HUMAN HEALTH RISK ASSESSMENTS OF DIOXIN AND DIOXIN-LIKE COMPOUNDS DOCUMENT REVIEWERS

INTERNAL PEER REVIEWERS

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ATTACHMENT C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 13 1998

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER Directive 9200.4-26

MEMORANDUM

SUBJECT: Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites

FROM: Timothy Fields, Jr. Acting Administrator /s/
Office of Solid Waste and Emergency Response

TO: Director, Office of Site Remediation and Restoration
Region I
Director, Emergency and Remedial Response Division
Region II
Director, Division of Environmental Planning and Protection
Region II
Director, Hazardous Waste Management Division
Regions IX
Director, Waste Management Division
Region IV
Director, Waste, Pesticides, & Toxics Division
Region V
Director, RCRA Multimedia Planning & Permitting Division
Region V
Director, Superfund Division
Regions III, V, VI, VII
Assistant Regional Administrator, office of Ecosystems Protection and Remediation
Region VIII
Director, Hazardous Waste Program
Region VIII
Director, Office of Environmental Cleanup
Region X
Director, Office of Waste and Chemical Management
Region X

PURPOSE

The purpose of this Directive is to recommend preliminary remediation goals (PRGs) or starting points for setting cleanup levels for dioxin in soil at Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA) corrective action sites. These recommended levels are to be used pending the release of the U.S. Environmental Protection Agency (EPA) comprehensive dioxin reassessment report and cross-program assessment of the impacts of the report. One ppb (TEQs, or toxicity equivalents) is to be generally used as a starting point for setting cleanup levels for CERCLA removal sites and as a PRG for remedial sites for dioxin in surface soil involving a residential exposure scenario. For commercial/industrial exposure scenarios, a soil level within the range of 5 ppb to 20 ppb (TEQs) should generally be used as a starting point for setting cleanup levels at CERCLA removal sites and as a PRG for remedial sites for dioxin in surface soil. These levels are recommended unless extenuating site-specific circumstances warrant a different level.

The dioxin levels discussed in this Directive are also generally recommended for actions taken under RCRA at corrective action sites. The recommended levels of 1 ppb (TEQs) for residential soils and within the range of 5 ppb to 20 ppb (TEQs) for commercial/industrial soils should generally be used as starting points in setting soil cleanup levels at RCRA corrective action sites. These levels are generally consistent with soil cleanup levels set at RCRA facilities throughout the country where dioxin is a principal contaminant of concern at the facility. However, because states are the primary implementors of the RCRA Corrective Action program, this Directive does not prescribe specific procedures for implementation under RCRA.

This Directive sets forth the policy basis for these recommended levels and prescribes procedures for implementing these recommendations.

BACKGROUND

To date, EPA has generally selected 1 ppb as a cleanup level for dioxin in residential soils at Superfund and RCRA cleanup sites where dioxin is a principal contaminant of concern at the facility. EPA has also, to date, generally selected a cleanup level for dioxin within the range of 5 ppb to 20 ppb for commercial/industrial soils at Superfund and RCRA cleanup sites where dioxin is a principal contaminant of concern at the facility. The levels that EPA has selected at these sites are protective of human health and the environment. Based on presently available information, and using standard default assumptions for reasonable maximum exposure scenarios, the upper-

bound lifetime excess cancer risk from residential exposure to a concentration of 1 ppb dioxin is approximately 2.5×10^{-4}, which is at the higher end of the range of excess cancer risks that are generally acceptable at Superfund sites. The calculated upper-bound excess cancer risk associated with a lifetime commercial/industrial exposure to 5 ppb, or the lower end of the range recommended for commercial/industrial soils, is approximately 1.3×10^{-4}, which is also within the CERCLA risk range. It should be noted that there is more difficulty in generalizing about the cancer risk associated with commercial/industrial cleanup levels than there is with residential cleanup levels due to the greater variability in exposures associated with commercial/industrial scenarios. Accordingly, the consultation process for Superfund sites referenced in the implementation section of this Directive should be used to ensure the selection of appropriate, protective dioxin levels at CERCLA commercial/industrial sites. Similarly, for RCRA corrective action sites, please refer to the implementation section of this Directive.

EPA is presently completing work on a comprehensive reassessment of the toxicity of dioxin, to be embodied in the documents entitled "Health Assessment Document for 2,3,7,8 tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds" and "Estimating Exposure to Dioxin-like Compounds." The reassessment report, which is scheduled to be issued in 1998, will represent the culmination of an Agency-wide effort to collect, analyze and synthesize all of the available information about dioxin. It has undergone significant internal and external review and is one of the most comprehensive evaluations of toxicity of a chemical ever performed by the Agency. Following release of the report, the Office of Solid Waste and Emergency Response (OSWER) will participate in a cross-program review of the implications of the report for the regulation and management of dioxin by EPA. We anticipate that this review will culminate in OSWER guidance addressing the management of dioxin at CERCLA and RCRA sites.

The Office of Solid Waste and Emergency Response does not believe it is prudent to establish new, and possibly varying, precedents for Superfund or RCRA dioxin levels just prior to the release of this reassessment report. As with any other pollutant, it is important that EPA ensure appropriate national consistency in remediation efforts. The Agency has used 1 ppb as a residential cleanup level and between 5 ppb and 20 ppb as a commercial/industrial cleanup level at CERCLA and RCRA cleanup sites for dioxin in soil in the past; it is anticipated that OSWER will be issuing guidance, informed by the reassessment effort, that will provide a basis for the selection of dioxin cleanup levels in the near future. In the interim, for sites that require the establishment of a final dioxin soil cleanup level prior to the release of the reassessment report and

development of OSWER guidance, EPA should generally use 1 ppb (TEQs) as a starting point for residential soil cleanup levels for CERCLA non-time critical removal sites (time permitting, for emergency and time critical sites) and as a PRG for remedial sites. EPA should generally use a level within the range of 5 ppb to 20 ppb (TEQs) as a starting point for cleanup levels at CERCLA non-time critical removal sites (time permitting, for emergency and time critical sites) and as a PRG for remedial sites for commercial/industrial soil. These levels should also be used as starting points in setting soil cleanup levels at RCRA corrective action sites.

For CERCLA remedial sites, consistent with 40 CFR § 300.430(f)(5)(iii)(D), EPA should commit to reviewing Records of Decision (RODs) (i.e., RODs in which this Directive has been used to develop dioxin soil cleanup levels) promptly following the release and analysis of the reassessment report and OSWER guidance, and, if necessary, to making changes to the RODs and cleanup actions, based on the information contained in the reassessment report and in the OSWER guidance. Similarly, in the case of non-time critical removal actions (time permitting, for emergency and time critical actions), EPA should commit to reviewing Action Memoranda promptly following the release and analysis of the reassessment report and OSWER guidance, and, if necessary, to making changes to the Action Memoranda and cleanup actions, based on the information contained in the reassessment report and the OSWER guidance. EPA should similarly commit to reviewing RCRA cleanup decisions (i.e., decisions for which this Directive has been used) promptly following the release and analysis of the reassessment report and OSWER guidance.

IMPLEMENTATION

Regional management should consult with the appropriate Office of Emergency and Remedial Response (OERR) Regional Centers on all proposed Fund and Potentially Responsible Party-lead site decisions under CERCLA, including other Federal agency-lead and state-lead site decisions, involving the development of dioxin soil cleanup levels for non-time critical removal sites (time permitting, for emergency and time critical removal sites) and remedial sites. Consultation should be initiated at the risk assessment stage. For Federal agency-lead sites, OERR will, in turn, notify the Federal Facilities Restoration Reuse Office of ongoing consultations. The Office of Site Remediation Enforcement will provide support if enforcement issues are identified. For consultation procedures, refer to the OSWER "Headquarters Consultation for Dioxin Sites", 9200.4-19, December 13, 1996, plus the OSWER "Consolidated Guide to Consultation Procedures for Superfund Response Decisions", 9200.1-18FS, May 1997.

In the case of EPA-lead RCRA corrective action sites, Regions should provide the Office of Solid Waste Permits and State Programs Division (OSW/PSPD) with proposed dioxin soil cleanup levels (i.e., prior to notice and comment) in order to ensure appropriate implementation of this Directive. For state-lead RCRA corrective action sites, it is also recommended that states use the dioxin levels recommended by this Directive as starting points in setting soil cleanup levels. States are encouraged to share their approaches with the Regions in a manner consistent with established procedures for EPA support and oversight of state RCRA Corrective Action programs.

The levels in this Directive are recommended unless extenuating site-specific circumstances warrant different levels, a more stringent state applicable or relevant and appropriate requirement (ARAR) establishes a cleanup level at CERCLA sites, or a more stringent state requirement applies at RCRA sites. We recommend that levels other than 1 ppb (TEQs) for residential soils and outside the range of 5 ppb to 20 ppb (TEQs) for commercial/industrial soils be used only where evidence exists that risks posed by the site differ from risks estimated using standard national default guidance values. These recommendations apply to RCRA corrective actions, CERCLA non-time critical removal actions (time permitting, for emergency and time-critical actions) and CERCLA remedial actions where cleanup levels are to be developed for dioxin in soil, regardless of whether dioxin itself drives the decision-making process.

The recommended levels found in this Directive, generally considered protective of human health and the environment, apply to surface soils. Please note that with respect to human health, these levels are based on the direct contact exposure pathway. The recommended levels in this Directive do not apply to other exposure pathways, such as migration of soil contaminants to ground water or to agricultural products. While the focus of this Directive is on soils, these recommended levels also apply to sediments in the event that this environmental medium is considered to be a direct exposure pathway for human receptors.

This document provides guidance to EPA staff. The guidance is designed to communicate national policy on dioxin cleanups for soil. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

If you have any questions concerning this Directive, please contact either Marlene Berg at (703)603-8701 in Headquarters or Elmer Akin of Region 4 at (404)562-8634, as Marlene and Elmer are

co-chairs of the Superfund Dioxin Workgroup. For the RCRA Corrective Action program, please contact Robert Hall of the Office of Solid Waste Permits and State Programs Division at (703)308-8484. Attached, for your information, is a list of Regional points of contact who are serving on the dioxin workgroup.

Attachment: Superfund Dioxin Workgroup: Regional Points of Contact

cc: Mike Shapiro, OSWER
Peter Grevatt, OSWER
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Superfund Dioxin Workgroup